



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Prospective Grant of Exclusive License: Small Molecule Therapeutics Against Hepatitis C Virus Infection**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a start-up exclusive commercial patent license agreement to practice the inventions embodied in U.S. provisional patent application no. 61/909,414 (NIH Ref. No. E-011-2014/0-US-01) filed November 27, 2013; International PCT application no. PCT/US2014/066680 (NIH Ref. No. E-011-2014/0-PCT-02) filed November 20, 2014; Taiwanese patent application no. 103141004 (NIH Ref. No. E-011-2014/0-TW-03) filed November 26, 2014; and U.S. provisional patent application no. 62/011,462 (NIH Ref. No. E-161-2014/0-US-01) filed June 12, 2014; all entitled, “Heterocyclic Compounds and Methods of Use Thereof;” and all continuing applications and foreign counterparts to Virotas Biopharmaceuticals, LLC, a company having a place of business in California. The patent rights in these inventions have (a) been assigned to the United States of America, as represented by the Secretary, Department of Health and

Human Services who has delegated authority for the licensing of inventions to the National Institutes of Health or (b) been exclusively licensed to the National Institutes of Health.

The prospective exclusive license territory may be “worldwide”, and the field of use may be limited to the following: “Prevention and treatment of Hepatitis C Virus infection.”

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Kevin W. Chang, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5018; Facsimile: (301) 402-0220; E-mail: [changke@mail.nih.gov](mailto:changke@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The subject technologies are small molecule compounds for the treatment of HCV infection identified using a novel cell-based high throughput assay. Some of these compounds are derivatives of chlorcyclizine that show potent antiviral properties against HCV. Chlorcyclizine is already on the market for the treatment of allergic reactions, have been used extensively in humans, and have excellent safety profiles with known pharmaceutical properties. The other compounds are also

heterocyclic compounds that show anti-HCV activity. The subject technologies can potentially be used in combination with each other and/or with other HCV therapeutics.

The prospective start-up exclusive commercial patent license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective start-up exclusive commercial patent license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: March 23, 2015.

**Richard U. Rodriguez,**  
*Acting Director,*  
*Office of Technology Transfer,*  
*National Institutes of Health.*

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